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REDACTED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A., Plaintiffs and Counterclaim-Defendants, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED, Defendants and Counterclaim-Plaintiffs.	:	Civil Action No. 3:10-CV-01723-JAP-TJB [redacted] **CONTAINS HIGHLY CONFIDENTIAL MATERIAL – FILE UNDER SEAL**

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Plaintiffs submit this memorandum in opposition to Defendants', Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (together, "Zydus"), Motion *in Limine* to Preclude the Evidence of [redacted]. Plaintiffs respectfully ask the Court to deny Zydus' motion *in limine* for the reasons set forth below.

PRELIMINARY STATEMENT

Zydus has once again filed a motion for summary judgment in the guise of a motion in limine. This time, Zydus has taken its original MIL (D.I. 237), arguing that [redacted], and goes one step further: [redacted]. Zydus is asking the Court to weigh the evidence on a number of disputed issues and make a final determination in the pre-trial motion stage. However, the purpose of a motion *in limine* is to decide the admissibility of evidence, not to argue the weight of the evidence. *See Pfizer Inc. v. Teva Pharms. USA, Inc.*, 461 F. Supp. 2d 271, 275 (D.N.J. 2006).

Zydus' position is that [redacted].

[1] As the Court knows, [redacted]. *See* D.I. 265.

Specifically, [redacted]

[redacted]:

[redacted]

Ex. 1, [redacted]

[redacted]:

[redacted]

Ex. 2, [redacted], Zydus-Supp000001-2, at 1-2 (emphasis added). Both Zydus' 30(b)(6) witness and Zydus' expert [redacted]. *See* ***Ex. 3***, 1/14/13 Gurram 30(b)(6) Dep. Tr. at 56:15-20, 57:18-25 ("definitely it complies"); ***Ex. 4***, 2/22/13 Brittain Dep. Tr. at 153:22-154:8, 156:7-12 ("So

[2] References to exhibits herein refer to exhibits attached to the Declaration of Arlene L. Chow.

therefore [redacted].

Zydus has [redacted] ***Ex. 5***, 8/23/12 email from J. Moriarty to A. Chow; ***Ex. 3***, 1/14/13 Gurram 30(b)(6) Dep. Tr. at 20:13-18. Yet, [redacted].

[redacted]

Zydus relies on *Bayer AG v. Elan Pharm. Research Corp.* ("*Elan*"), 212 F.3d 1241 (Fed. Cir. 2000) and [redacted]. The appropriate time for the Court to determine this issue is at trial, not in a motion *in limine*. *See Pfizer*, 461 F. Supp. 2d at 275 (determining disputes involving the weight of the evidence are improper for a motion *in limine*).

[redacted]

[redacted]. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]. *Compare* ***Ex. 6***, Bugay Opening Expert Rep. (Takeda) at ¶ 70 ([redacted]) *with* ***Ex. 7***, Brittain Amended Suppl. Rebuttal Expert Rep. (Zydus) at ¶ 90 ("a person of ordinary skill in the art . . . [redacted]).

The second question [redacted]

[redacted]

[redacted]

[redacted]

[redacted] *See* ***Ex. 3***, 1/14/13 Gurram 30(b)(6) Dep. Tr. at 91:3-92:5; ***Ex. 8***, Bugay Rebuttal Expert Rep. at ¶ 8.

[redacted]

Although this case is not analogous to *Elan*, it *is* akin to *Bayer AG v. Biovail Corp.* ("*Biovail*"), which concerned the same patent at issue in *Elan* [redacted]. However, *Biovail* differed from *Elan* because Bayer's actual testing evidence indicated that Elan's commercial product could, in fact, infringe. *See* 279 F.3d 1340, 1346-47 (Fed. Cir. 2002). The Federal Circuit therefore reversed the ruling in Elan's favor. *See id.* (finding Bayer's evidence created a genuine dispute as to whether Elan's ANDA directly addressed the issue of infringement). Here, [redacted]

[redacted]. *See* ***Ex. 9***, Bugay Amended Suppl. Expert Rep. at ¶¶ 52, 59.

Zydus' motion *in limine* should be denied.

FACTUAL BACKGROUND

This is a patent infringement action under the Hatch-Waxman Act in which Plaintiffs allege that the drug product described in Zydus' ANDA 200-816 infringes U.S. Patent Nos. 6,328,994 ("the '994 patent"), 7,431,942 ("the '942 patent"), 7,875,292 ("the '292 patent") ('994, '942, and '292 patents, collectively, the "Takeda patents") and 5,464,632 ("the '632 patent"). [redacted] since the outset of the litigation, because each of the Takeda patents claims enteric-coated or finished-coated "fine granules" of an average particle diameter of 400 µm or less.[3] *See* ***Ex. 10***, '994 patent at Claim 1; ***Ex. 11***, '942 patent at Claim 1; ***Ex. 12***, '292 patent at Claim 1. On October 5, 2011, this Court construed the "400 µm or less" limitation as incorporating a measurement variation of ±10%. D.I. 113 at 4-10.

[redacted]. *See* ***Ex. 13***, Paragraph IV Notice Letter at 61-63, 73-74.

Then, [redacted]

---

[3] Please note the discussion regarding the "400 µm or less" term is equally applicable to "fine granules having an average particle diameter of 300 to 400 µm" term. *See* ***Ex. 11***, '942 patent at Claim 1; ***Ex. 10***, '994 patent at Claim 2.

[4] On February 10, 2012, as a result of the Court's claim construction, Zydus sought leave to amend its non-infringement contentions [redacted]. *See* D.I. 143 at 10-12. This Court rejected Zydus' attempt as untimely and also denied Zydus' subsequent motion for re-consideration of that Order *See* D.I. 191 at 23-24; s*ee also* D.I. 223.

[redacted][5] *See* D.I. 156 at 2-3. [redacted]

[redacted]" ***Ex. 5***, 8/23/12 email from J. Moriarty to A. Chow; *see also* ***Ex. 14***, 3/6/12 email from A. Chow to S. Moore. This was the EMM batch. Zydus contended that [redacted]. *See* ***Ex. 2***, EMM Particle Size Data, Zydus-Supp000001-2, at 1.

[redacted] *See* ***Ex. 1***, [redacted], Z0155881-907, at 25-26. [redacted]. *See* D.I. 237. In that same motion *in limine*, [redacted]. *See* D.I. 236 at 13-16.

[redacted]

[5] While Zydus' motion for leave to amend its non-infringement contentions was pending, Plaintiffs moved for spoliation sanctions [redacted]. *See* D.I. 146.

[redacted]. D.I. 265 at 1-2 ([redacted]).

[redacted]. *See* ***Ex. 9***, Bugay Amended Suppl. Expert Rep. at ¶¶52, 59, 62-65.

ARGUMENT

I. [redacted][6,7]

[redacted]. *See* D.I. 294 at 14. However, Zydus' position is wholly inconsistent with [redacted].

---

[6] Zydus also argues that [redacted] D.I. 294 at 18. However, [redacted] *See* ***Ex. 15***, Meyer-Stout Expert Rep. at Table 1 ([redacted]); *see also* ***Ex. 13***, Paragraph IV Notice Letter at 61-63, 73-74. In contrast, Zydus believes [redacted]. *See supra*, Part I. Thus, [redacted].

[7] Despite Zydus' repeated assertions that [redacted].

As discussed above, [redacted]:

[redacted]

Ex. 2, [redacted], Zydus-Supp000001-2, at 1-2 (emphasis added).

Further, both Zydus' 30(b)(6) witness, Srinivas Gurram, and Zydus' expert, Dr. Brittain, testified [redacted]. *See* ***Ex. 3***, 1/14/13 Gurram 30(b)(6) Dep. Tr. at 56:15-20, 57:18-25 ([redacted]); ***Ex. 4***, 2/22/13 Brittain Dep. Tr. at 153:22-154:8, 156:7-12 ("[redacted]).

Moreover, contrary to Zydus' current assertions, [redacted]

[redacted] *See* ***Ex. 5***, 8/23/12 email from J. Moriarty to A. Chow; ***Ex. 3***, 1/14/13 Gurram 30(b)(6) Dep. Tr. at 20:13-18.

Accordingly, Zydus' reliance on the fact that [redacted] Therefore, [redacted] but is highly relevant and admissible.

II. [redacted]

Zydus re-argues that [redacted]. *See* D.I. 294 at 14-15, 18-19. This Court previously rejected that argument. *See* ***Ex. 16***, 10/22/12 Motion Hearing Transcript at 13:15-17:6, 41:2-9 ([redacted]).

First and foremost, [redacted] involves weighing the parties' evidence, which is more appropriate for trial, not in a motion *in limine*. *See Pfizer*, 461 F. Supp. 2d at 275. For that reason alone, the Court should deny Zydus' motion *in limine.* As shown below, [redacted] and thus, *Elan* is not applicable.

A. *Bayer AG v. Elan Pharm. Research Corp.*

Elan involved a patent of Bayer's claiming a drug containing nifedipine crystals of a specific surface area ("SSA") – 1.0 to 4.0 m^2/g. *See* 212 F.3d at 1246. Elan amended its ANDA to specify that its drug product would only contain nifedipine crystals with a SSA of 5 m^2/g or greater. *See id.* With its ANDA, Elan filed a certificate of analysis ("COA") performed by an

independent laboratory, which stated the measured SSA of the nifedipine crystals used in Elan's drug product was 6.15 m^2/g. *See id.* Moreover, Elan's nifedipine supplier was prohibited from selling nifedipine with a SSA under 4.7 m^2/g in the United States. *See id.* at 1248. Also, at FDA's request, Elan defined its method of testing to ensure the nifedipine's SSA [size] to be 5 m^2/g or greater: Elan would measure the SSA of its nifedipine no more than five business days before tablet manufacture and would discard any nifedipine having a SSA of less than 5 m^5/g. *See id.* at 1246.

In response, Bayer did not contend, nor did it offer any evidence, that Elan's drug would literally infringe its patent. *See id.* at 1246, 1249. Instead, Bayer speculated that the SSA of the nifedipine crystals would reduce over time to a measurement that fell within the claimed SSA size. *See id.* at 1248-49. Finding Bayer's speculation did not raise an issue of fact, the court granted Elan's motion for summary judgment. *See id.* at 1254. The Federal Circuit affirmed, agreeing that Elan's ANDA specification "defines its product in a way that directly addresses the question of infringement – the SSA [size] of nifedipine crystals." *Id.* at 1249-50.

B. *Bayer AG v. Biovail Corp.*

After *Elan*, in a subsequent case brought by Bayer on the same patent, the Federal Circuit held that a "nearly identical" Elan ANDA did not directly resolve the issue of infringement, and ordered the district court to consider evidence outside the ANDA. *See Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1346-47 (Fed. Cir. 2002). *Elan* had involved the Elan's ANDA for 30 mg Adalat CC. *Biovail* concerned the same patent at issue in *Elan* and Elans' "nearly identical" ANDA for 60 mg Adalat CC. *See id.* In the second case (*Biovail*), Elan contended that its ANDA directly resolved the issue of infringement. *See id.* at 1343, 1346. Although the *Biovail* court recognized that the legal issues were facially similar to *Elan*, the factual evidence proffered

in *Biovail* differed because, based on actual testing, Bayer now had evidence that Elan's drug product infringed Bayer's patent, *i.e.*, Elan's ANDA did not directly resolve the issue of infringement. *See id.* at 1346 ("Bayer did not . . . provide evidence of infringement by the ANDA tablet in the [*Elan*] 30 mg ANDA case."). In other words, Bayer's new evidence, based on testing of Elan's commercial product, created a genuine dispute as to whether Elan's ANDA specification defined the compound with sufficient particularity to answer the infringement inquiry. *See id.* at 1346-47.

C. *Elan* is Not Applicable Here

Because [redacted] – *Elan* is simply not applicable in this case. Here, [redacted].

[redacted]

1. Zydus' [redacted]

[redacted]. *See* ***Ex. 17***, Zydus' Responses to Ps' Suppl. Interrogatories at 7, 8, 10 [redacted] *See, e.g.*, ***Ex. 9***, Bugay Amended Supplement Expert Rep. at ¶¶ 19, 63 ("[redacted]").

[redacted]. *See* ***Ex. 19***, 2/15/13 Bugay Dep. Tr. at 137:2-22.

[redacted]

2. Zydus' [redacted]

The parties also dispute [redacted]. *See* ***Ex. 3***, 1/14/13 Gurram 30(b)(6) Dep. Tr. at 91:3-92:5. [redacted]. *See* ***Ex. 20***, 9/14/12 Bugay Dep. Tr. at 222:15-223:4 ("[redacted]"); ***Ex. 4***, 2/22/13 Brittain Dep. Tr. at 137:17-20 ("[redacted]") (emphasis added).

[redacted]. *See, e.g.*, ***Ex. 8***, Bugay Rebuttal Expert Rep. at ¶¶ 6-10 ("[redacted]").

Again, [redacted]

[redacted].

See supra Part II.C.1.

D. *Biovail* is Directly on Point

This case is more akin to the circumstances in *Biovail*. Here, [redacted]

"genuine disput[e] as to whether the ANDA specification defines the compound with sufficient particularity to answer the infringement inquiry." *See Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002). [redacted]. *See supra* Part I. Y[redacted]. *See* ***Ex. 9***, Bugay Amended Suppl. Expert Rep. at ¶¶ 52, 59.

[redacted]. *See* D.I. 294 at 30. Although the Federal Circuit found the question of infringement turned on whether the claims were construed to cover both pre-tableted and post-tableted nifedipine crystals, it held that if "those claim terms also encompass [post-tableted crystals]. . . the district court **must** consider [Bayer's new evidence] in its 60 mg ANDA infringement analysis." *See* 279 F.3d at 1347 (finding Bayer's new evidence created a dispute regarding whether Elan's ANDA directly addressed the issue of infringement) (emphasis added). Because the Federal Circuit considered the possible outcomes in relation to claim construction when requiring the district court to consider evidence outside the ANDA, Zydus' argument is irrelevant.

Zydus' contention that *Biovail* is distinguishable because Bayer proffered evidence of commercial tablets is equally without merit. *See* D.I. 294 at 30-31. The *Biovail* court did not

focus on the commercial nature of Bayer's evidence. Instead, the Federal Circuit's decision turned on the fact that Bayer had evidence showing Elan's product infringed Bayer's patent and thus, Elan's ANDA did not directly resolve the issue of infringement. *See Biovail*, 279 at 1346-50 (noting that Bayer did not provide similar evidence in the *Elan*). In any case, [redacted].

Thus, *Biovail* is directly on point. As in *Biovail*, [redacted].

E. [redacted]

The *Elan* court also held Elan's ANDA directly resolved the issue of infringement by the doctrine of equivalents because the patentees disclaimed all nifedipine crystals outside the claimed range of 1.0 to 4.0 m^2/g. *See* 212 F.3d at 1250-54. However, this is not the case for the Takeda patents. Here, the patentees did not disavow "fine granules" with average particle diameters above 440 µm. [redacted]. *See* ***Ex. 21***, 2/25/13 Morrison Dep. Tr. at 27:15-19 ([redacted]).

F. Conclusion

In sum, Zydus' reliance on *Elan* is flawed. [redacted]

[redacted]" A motion *in limine* is not the appropriate time to hash out this dispute. Accordingly, the Court should deny Zydus' motion *in limine* and consider the disputed issues during trial.

CONCLUSION

For the reasons above, Plaintiffs respectfully request that the Court deny Zydus' motion *in limine* to preclude evidence [redacted].

Respectfully submitted,

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